



JUL 22 2002 4 67 2 32 13 -5 P2:06

Mr. Robert Doster
Senior Vice President of Scientific Affairs
Enzymatic Therapy, Inc.
825 Challenger Drive
Green Bay, Wisconsin 54311

Dear Mr. Doster:

This is in response to your letter of June 25, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Enzymatic Therapy, Inc. is making the following claim for the product named **Heartburn Free™** :

“10 pills, 20 days, Heartburn Free™.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, including the use of the term “heartburn” in the name of the product, suggests that it is intended to treat, prevent, or mitigate a disease, heartburn’. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Although FDA concluded that “occasional heartburn” and “occasional acid indigestion” may be nonspecific symptoms that could be appropriate structure/function claims, the claim for your product is not qualified such that it is not a disease claim. (see 65 FR 1000 at 1031; Jan. 6, 2000).


975-0163

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Please contact us if you require further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret", with a stylized flourish at the end.

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

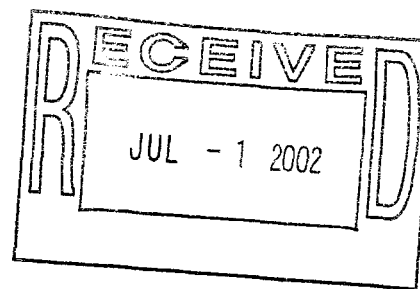
FDA, Minneapolis District Compliance, HFR-MW240

EnzymaticTherapy®

NATURAL MEDICINES™

June 25, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835



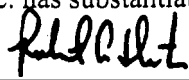
RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Heartburn Free™*	Orange (Citrus sinensis) Peel Extract	10 pills, 20 days, Heartburn Free™.*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

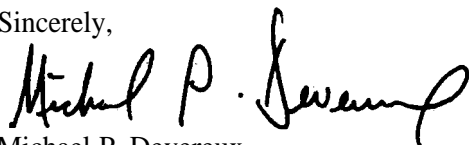
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 6-25-02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Heartburn Free 19e

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